In the United States Court of Federal Claims

No. 10-850V
(Filed: January 10, 2014)*
* Opinion originally filed under seal on December 19, 2013

PAMELA ANN DILLON, Petitioner, v. SECRETARY OF HEALTH and HUMAN SERVICES, Respondent.	)	Vaccine Act; Transverse Myelitis; Althen Analysis

Michael G. McLaren, Memphis, TN, for petitioner. *William E. Cochran, Jr.*, Memphis, TN, of counsel.

Ryan Daniel Pyles, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent. *Stuart Delery*, Assistant Attorney General, *Rupa Bhattacharyya*, Director, Torts Branch, Civil Division, *Vincent J. Matanoski*, Deputy Director, Torts Branch, Civil Division, and *Gabrielle M. Fielding*, Assistant Director, Torts Branch, Civil Division, of counsel.

O P I N I O N

Firestone, Judge.

Pending before the court is petitioner Pamela Ann Dillon's ("Ms. Dillon") motion for review of the chief special master's decision denying her compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300a-1 to -34 ("the Vaccine Act"), as amended. Dillon v. Sec'y of Health & Human Servs., No. 10-850, 2013 WL 3745900 (Fed. Cl. June 25, 2013) ("Decision").

The petitioner alleges that the influenza vaccine, which she received on October 1, 2008, caused her to develop autoimmune transverse myelitis[1] and associated injuries. An evidentiary hearing was held over two days in August 2012. The chief special master, applying the Federal Circuit's precedent in Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339 (Fed. Cir. 2010), and Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343 (Fed. Cir. 2011), found that the petitioner was not entitled to recover because she had not suffered from autoimmune transverse myelitis but rather had developed transverse myelitis as a result a previously-undiscovered hemorrhage of a cavernoma,[2] which was surgically removed on July 31, 2012. In the alternative, the chief special master, applying the Althen test, found that the petitioner had failed to establish by a preponderance of the evidence a logical sequence of cause and effect showing that the vaccination was the reason for her injury. The chief special master determined that petitioner had not established that her symptoms were "primary and autoimmune"—that is, caused by the vaccine—and further found that they were "a secondary effect of the

[1] Transverse myelitis is a broad diagnosis that describes various injuries, including an "autoimmune response or [response to a] viral infection" and an "inflammatory event secondary to [trauma, such as] a bleed in the spinal cord." Transcript at 175; see also Transcript at 262-63.

[2] A cavernoma is a vascular tumor composed mainly of large, dilated blood vessels, often containing large amounts of blood. Dorland's Illustrated Medical Dictionary 831 (32nd ed. 2012). A cavernoma is usually located under the skin or subcutaneous tissue, but may also occur in viscera such as the liver, spleen, pancreas, or brain. Id. The lesion often presents early in life, but usually after birth. Id. It tends to be bright to dark red when superficial, and blue when more deeply embedded. A cavernoma in the spinal cord presents as a lesion on it, but exists separately from the surface of the spinal cord. Transcript at 176. Such a cavernoma may grow over time to cause the cord surrounding it to expand. Transcript at 133. Because it is composed of thin blood vessels, growth may cause it to bleed. It can remain asymptomatic for a long period of time, but once it begins to grow or bleed it can create "the same constellation of neurological problems . . . [one] might see when there is inflammation in the spinal cord." Transcript at 23-24; see also Transcript at 88; Resp.'s Ex. G.

trauma caused by her hemorrhaging cavernoma." Decision at 31. In her motion for review, the petitioner contends that the chief special master's decision denying her recovery on these grounds was arbitrary, capricious, and not in accordance with law.

As discussed below, because the court finds that the chief special master's decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, petitioner's motion is denied and the decision of the chief special master is sustained.

I. BACKGROUND

A. Procedural History

On December 21, 2010, Ms. Dillon filed a petition under the Vaccine Act. On March 4, 2011, after reviewing the petition, the Secretary of Health and Human Services recommended against compensation. Resp.'s Report. Petitioner then filed additional medical records as well as expert reports from her treating neurologist, Dr. Sidney A. Houff. Pet.'s Ex. 12. Respondent then filed an expert report by Dr. Thomas Leist, an expert in neuroimmunology, arguing that petitioner's injury "stemmed from a preexisting vascular malformation." Resp.'s Ex. A at 8, 10. Petitioner then filed an expert report from Dr. Lawrence Steinman, an expert in neuroimmunology, and Dr. Robert M. Kessler, an expert in neuroradiology. Pet.'s Ex. 44. Petitioner also noted that Dr. Houff's status as an expert witness was uncertain due to personal health issues. Pet.'s Status Report at 1. Finally, respondent filed an expert report by Chip Truwit, an expert in neuroradiology, along with a supplemental expert report by Dr. Leist, to address Dr. Kessler's report. Resp.'s Exs. B-C.

On August 20, 2012, petitioner filed imaging confirming that a lesion that was surgically removed from her spinal cord on July 31, 2012 had been a cavernoma. Pet.'s Ex. 63 at 64. On August 23-24, 2012, hearings were held in Nashville, Tennessee, during which testimony was heard from the expert witnesses. Decision at 3. On June 25, 2013, following attempts of the parties to resolve the case informally, the chief special master issued a decision denying compensation. On July 25, 2013, petitioner filed a motion for review.

B. Facts

1. Petitioner's Medical History

Ms. Dillon was born on July 23, 1957. Pet.'s Ex. 2 at 1. Her medical history includes depression, anxiety, kidney stones, obesity, sleep apnea, and a hysterectomy. Pet.'s Ex. 11 at 1. She had no noted neurological problems before October 2008. Pet.'s Ex. 1. Her medical records indicated that on February 14, 2006, she received a skin test for tuberculosis and a flu vaccination without any identified problems. Pet.'s Ex. 2 at 2. She also received a measles, mumps, and rubella vaccination on May 11, 2006 with no reported side effects. Id. Two years later, on September 30, 2008, petitioner conferred with Dr. Eric Smith, a doctor of osteopathic medicine, about the possibility of gastric bypass surgery. Pet.'s Ex. 11 at 5. Dr. Smith's notes indicate that petitioner was suffering from morbid obesity, back pain, and elevated concentrations of lipids in her blood plasma. Id. Petitioner received the trivalent flu vaccine at issue on October 1, 2008. Pet.'s Ex. 2 at 14. On October 19, 2008, petitioner went to the emergency room at St. Claire Regional Medical Center with complaints of severe back pain that had started

the day before. Pet.'s Ex. 3 at 163. An abdominal ultrasound and an abdominal computed tomography ("CT") scan[3] were performed with negative results for kidney stones and positive results for diffuse fatty gallstones. Id. at 168-69. She was diagnosed with acute pain, lumbar strain, and a left ovarian cyst; she was then treated with pain relievers and released. Pet.'s Ex. 1; Pet.'s Ex. 3 at 161.

On October 21, 2008, petitioner returned to the emergency room with complaints of back pain, radiating leg pain, constipation, and moderate sensory loss in her legs. Pet.'s Ex. 3 at 177. She was transferred to the University of Kentucky Medical Center ("UKMC") that day and remained there until October 24, 2008. See Transcript at 90, 177-79. On October 22, 2008, a magnetic resonance image (MRI)[4] was taken of her spine, which showed degenerative disc changes in the L5-S1 disc. Pet.'s Ex. 4 at 79, 86. Another MRI showed ascending lesions of white matter in the lumbothoracic spine, which are indicative of inflammation. Pet.'s Ex. 4 at 35-36. This second MRI showed signal abnormality and suggested a small, focal lesion within the distal thoracic spinal cord, centered at the T9/T10 disc space. Id. at 36, 85-86. A hemosiderin deposit, which signals that blood was in the area, was detectable near the lesion. Transcript at 269-72; see Resp.'s Ex. C at 4. The MRI also showed a signal enhancement at the T2 level that

[3] A CT scan combines X-ray images from different angles to create cross-sectional images of the bones and soft tissues inside a body. Mayo Clinic: CT scan, http://www.mayoclinic.com/health/ct-scan/MY00309 (last visited Dec. 18, 2013).

[4] An MRI uses a magnetic field and radio waves to create images of the body, and can help to identify changes in the body as well as detecting infection or tumors. WebMD: Magnetic Resonance Imaging (MRI), http://www.webmd.com/a-to-z-guides/magnetic-resonance-imaging-mri (last visited Dec. 18, 2013).

spanned an area of six vertebral segments. Pet.'s Ex. 4 at 36, 85-86. Additionally, nearly complete resolution of vaguely observable edema was discernible within the mid and distal portions of the thoracic spinal cord. Id. This finding was deemed to be consistent with transverse myelitis. Id. The petitioner was administered methylprednisolone, an intravenous steroid which is used to treat transverse myelitis, but she showed only modest improvement. Id.; Transcript at 47-48.

On October 24, 2008, a lumbar puncture study was performed, showing an abnormal elevated red blood cell count in tubes one and four. Pet.'s Ex. 4 at 89. At this time, none of petitioner's physicians appear to have considered the possibility of a spinal bleed. See id. On October 27, 2008, Ms. Dillon was examined by a neurologist, who stated that she was suffering from transverse myelitis, "secondary to possibly the flu vaccine." Id. at 19. On October 29, 2008, she was diagnosed with transverse myelitis. Id. at 19, 36. On discharge, she was sent for inpatient rehabilitation at Cardinal Hill Rehabilitation Hospital from October 29, 2008 to Dec. 11, 2008. Pet.'s Ex. 5 at 4.

On June 9, 2009, Ms. Dillon was readmitted to UKMC following a neurology consult there. Pet.'s Ex. 4 at 397-98, 404. While petitioner showed some improvement from 2008, she had not returned to her baseline condition. Pet.'s Ex. 5 at 944-45. Additionally, she reported new vision problems, for which she was admitted to the hospital. Pet.'s Ex. 4 at 397-98, 404. While hospitalized, she received further neurologic evaluation. She also received an MRI, which revealed to the radiologist that the lesion shown in earlier MRIs was "most suggestive of a cavernous malformation with remote hemorrhage." Pet.'s Ex. 28 at 58. Her cerebrospinal fluid showed elevated myelin basic

protein levels, which is indicative of trauma, infection, stroke, or disease in the central nervous system. Id. at 49.

On April 12, 2011, four months after filing this vaccine claim, Ms. Dillon met with Dr. Houff, who noted that the problems with sensation in her legs had shown minimal improvement since June 2009, and he attributed her ongoing symptoms to the earlier episode of transverse myelitis, which had occurred three weeks after she had received the flu vaccine. Pet.'s Ex. 59 at 83-84. On May 10, 2011, she received an MRI of her thoracic spine, which showed a lesion at the T9/T10 disc base. Pet.'s Ex. 28 at 21. According to the evaluating physician,

> the size, configuration, and signal intensity characteristic of the lesion [has] remained stable over the past 2 years. There [also] remains speckled punctuate enhancement of the lesion and evidence of prior hemorrhage. The lack of interval change overall . . . favors the diagnosis of a vascular malformation or cavernous angioma.

Id.

On May 27, 2012, Ms. Dillon received another MRI, which showed that the lesion had grown approximately 200 times in volume since October 2008. Pet.'s Ex. 50 at 4-5; Transcript at 149, 151-52. On June 7, 2012, Ms. Dillon received a consult from Dr. Abdulnasser Alhajeri, a radiologist, concerning the lesion, in which Dr. Alhajeri observed that the petitioner's symptoms "had progressed over the last year and a half." Pet.'s Ex. 50 at 4-5. In a separate consultation on that day, Dr. Houff expressed concern that Ms. Dillon may have developed an arteriovenous malformation[5] in addition to what he had

[5] An arteriovenous malformation is composed of masses of arteries and arterialized veins that disrupt normal blood flow by operating as high flow shunts for blood. Central Nervous System

believed to be a vaccine-related event. Pet.'s Ex. 55 at 4. As a result of escalating symptoms, she became confined to a wheelchair. Id. The lesion was ultimately determined to be a cavernous malformation and was surgically resected on July 31, 2012. Pet.'s Ex. 63; Pet.'s Ex. 64 at 1.

2. Expert Testimony

During trial before the chief special master, petitioner presented experts to support her theory of entitlement based on her contention that she suffered a post-vaccination transverse myelitis caused by the flu vaccine she received on October 1, 2008. The respondent presented experts who took the position that Ms. Dillon's neurological problems stemmed from the cavernoma that was evident but ignored when Ms. Dillon was first examined and was removed on July 31, 2012 after it had grown dramatically in size. It is undisputed that once a cavernoma becomes symptomatic, either by growing or bleeding, it can create "the same constellation of neurological problems . . . [one] might see when there is inflammation in the spinal cord." Transcript at 23-24; see also Transcript at 88; Resp.'s Ex. G. Petitioner and respondent presented testimony from two experts at trial. Their credentials appear in chief special master's decision and are not repeated here. Decision at 13-16. The chief special master accepted each of these experts as well-qualified. Id.

Vascular Malformations: A Patient's Guide, http://www.neurosurgery.mgh.harvard.edu/neurovascular/vascintr.htm#AVM (last visited Nov. 22, 2013). Between these masses, tissue is compressed. Id. This is distinguishable from a cavernoma, which is composed of blood-filled channels that are immediately adjacent to each other without brain tissue between them. Id.

Petitioner's experts presented evidence that, although a cavernoma was present in October, 2008, her injuries were caused by the flu vaccine that she received on October 1, 2008 and not by the cavernoma in her spinal cord. Dr. Steinman, petitioner's expert neuroimmunologist, presented an opinion that the flu vaccine caused an autoimmune response based on the biologic mechanism of molecular mimicry and relied on peer reviewed journals and his experience as an immunologist. Pet.'s Ex. 29; Transcript at 25-26. According to him, a flu vaccine could trigger an immune response targeting the myelin basic protein that provides a protective sheath around the body's nerve fibers due to the structural similarity between components of the vaccine and the spinal cord. Id. In his view, the best evidence of autoimmune transverse myelitis was the results of Ms. Dillon's October 2008 MRIs and the June 2009 cerebrospinal fluid test showing elevated myelin basic protein levels, though he admitted that this could be caused by a trauma, as well. Pet.'s Ex. 29 at 21; Pet.'s Ex. 28 at 49. Additionally, he relied on the evidence of speckled punctuate enhancement in Ms. Dillon's October MRIs and the timing of her symptom onset in reaching his conclusion. Pet.'s Ex. 29 at 22. Further, he opined that the cavernoma was not a significant factor in the injury. Transcript at 91-92. He explained that diagnostic confusion may arise when distinguishing between inflammatory disorders such as transverse myelitis and disorders involving spinal cord tumors. Id. He explained that the lesion found could have been caused by the inflammation associated with transverse myelitis, though he admitted that he was not aware of medical literature indicating that transverse myelitis could cause a cavernoma to grow in the spinal cord. Id. at 34, 91-92.

Dr. Kessler, petitioner's expert neuroradiologist, presented testimony based on radiologic evidence from reviewing MRI images of Ms. Dillon's brain, orbits, and spine taken between October 21, 2008 and March 27, 2012. Pet.'s Ex. 44. He noted degenerative changes in her lower back and mid-shoulder area and increased T2 signals in her distal thoracic spinal cord. Id. at 1-3. He argued that these findings were consistent with transverse myelitis, although he admitted that they were non-specific and would also be consistent with inflammatory swelling, demyelination, or a tumor. Id. at 4; Transcript at 117-18. He also relied on the timing of her injury in coming to his conclusion. Pet.'s Ex. 44 at 4. While he acknowledged that Ms. Dillon's lesion seemed like a cavernoma, he dismissed a connection between it and her neurological problems associated with transverse myelitis. Transcript at 145, 161.

Respondent's experts presented evidence that Ms. Dillon did not have an autoimmune reaction to the flu vaccine she received on October 1, 2008 and that her neurological problems were the result of a bleeding cavernoma in her spinal cord. Dr. Leist, respondent's expert neuroimmunologist, presented testimony challenging the petitioner's theory that Ms. Dillon's injury could be best described as autoimmune transverse myelitis. Transcript at 173. He noted that Ms. Dillon had previously received two flu vaccines without any reported issues, that the results of her imaging and spinal tap established that there had been bleeding in her spine, that she had a cavernoma, and that the relatively sudden onset of symptoms occurred around the time that the cavernoma likely began to bleed. Resp.'s Ex. A at 6-7. Referring to Ms. Dillon's MRI images, he stated that the faint enhancement shown over time was not consistent with an

inflammatory, demyelinating lesion; while that would decrease in size over time, Ms. Dillon's continued to grow. Id. He also noted that Ms. Dillon's neurologic problems did not improve much after the onset of symptoms, and that they did not respond to a steroid treatment as would be expected with inflammatory or demyelinating conditions. Transcript at 174. Referring to her cerebrospinal fluid testing, he noted that it showed modestly elevated myelin basic protein, which he explained is a non-specific marker of tissue injury. Resp.'s Ex. B at 1. He further explained that the tests did not show elevated levels of inflammatory cells, which would be present if the claimed massive inflammatory changes had occurred. Id.

Dr. Truwit, respondent's neuroradiologist, presented testimony regarding the MRI images showing a vascular malformation in the distal aspect of Ms. Dillon's spinal cord and traces of hemosiderin as speckled punctuate enhancement. Transcript at 259-60, 272-73. He stated that early images showed a lesion that could be caused by various events, including trauma or tumor, but that later images made it more likely that the lesion was the early presentation of a small vascular malformation. Transcript at 278. Additionally, he noted that the hemosiderin deposition in Ms. Dillon's spinal cord became more evident over time. Resp.'s Ex. C at 5. Relying on these findings along with the finding of red blood cells in her cerebrospinal fluid, he opined that the lesion was a cavernoma. Id. He further opined that Ms. Dillon's symptom onset occurred around the time that the cavernoma first began to hemorrhage. Id. Relying on his experience, he stated that the hemosiderin deposition shown does not occur in cases of autoimmune transverse myelitis. Id. He did not think that there was any connection

between the vaccine and the cavernoma itself, and stated that drawing such a connection did not fit the facts. Id.

C. The Special Master's Decision

On June 25, 2013, the chief special master issued a decision denying Ms. Dillon compensation under the Vaccine Act. The chief special master determined that Ms. Dillon did not suffer from primary autoimmune transverse myelitis following her flu vaccination in October, 2008. The chief special master concluded, based on the expert testimony she received and medical records she reviewed, that Ms. Dillon's neurological problems were the result of a hemorrhaging cavernoma. Relying on the Federal Circuit's decisions in Broekelschen and Lombardi, the chief special master concluded that where, as here, she found that petitioner suffered from an injury other than the one alleged by petitioner, this determination precluded the finding of causation in petitioner's favor.

For these same reasons, the chief special master concluded in the alternative that petitioner could not prevail under the Althen test established by the Federal Circuit. Specifically, the chief special master found that petitioner failed to provide a theory causally connecting the vaccine to her injury. The chief special master also found that petitioner could not establish a logical sequence of cause and effect showing that the vaccine led to an autoimmune response and was thus the cause of her injury. On July 25, 2013, petitioner filed this motion for review. Having been briefed and argued, the matter is now ripe for decision.

II. STANDARD OF REVIEW

This court has jurisdiction to review the decisions of a special master in a Vaccine Act case upon a motion from the petitioner. 42 U.S.C. § 300aa-12(e)(2). The court uses three distinct standards of review in Vaccine Act cases: findings of fact are reviewed under the arbitrary and capricious standard, questions of law under the not in accordance with law standard, and discretionary rulings under the abuse of discretion standard. Masias v. Sec'y of Health & Human Servs., 634 F.3d 1283, 1287–88 (Fed. Cir. 2011); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); see 42 U.S.C § 300aa-12(e)(2)(B). However, the court does not "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotation marks omitted) (quoting Munn, 970 F.2d at 871). If the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision," then "reversible error is extremely difficult to demonstrate." Id. at 1360 (internal quotation marks omitted) (quoting Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

III. DISCUSSION

A. Vaccine Act Standards

The Vaccine Act created the National Vaccine Injury Compensation Program ("Vaccine Program"), which provides compensation for vaccine-related injuries or deaths. Under the Vaccine Program, there are two means of recovery: claims based on injuries listed in the Vaccine Injury Table ("Table") and claims based on injuries not

listed in the Table, known as off-Table claims. In a Table claim, a petitioner is granted a presumption of causation if he or she shows that he or she received a vaccine listed in the Table, that he or she suffered an injury listed in the Table, and that the injury occurred within the prescribed time period. See Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009) (describing Table cases). In an off-Table case, a petitioner who received a vaccine listed in the Table but suffered an injury not listed in the table does not receive a presumption of causation, and instead must prove causation by a preponderance of the evidence. See Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010) (describing off-Table cases).

In order to prove causation in an off-Table case, the petitioner must show that the injury "was caused by a vaccine" listed in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). The Federal Circuit explained the evidentiary burden placed on petitioners in Althen v. Sec'y of Health & Human Servs.: in order to show causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d 1274, 1278 (Fed. Cir. 2005). This showing of causation requires "a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically

certain.'" Broekelschen, 618 F.3d at 1345 (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)).[6]

Once the petitioner satisfies this burden under Althen, he or she is "entitled to recover unless [the respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151-52 (Fed. Cir. 2007) (quoting Whitecotton v. Sec'y of Health & Human Servs., 17 F.3d 376 (Fed. Cir. 1994), rev'd on other grounds sub nom. Shalala v. Whitecotton, 514 U.S. 268 (1995)) (citing Knudsen, 35 F.3d at 547). Importantly, the evidence presented to establish an unrelated cause of injury may also be considered in determining whether the petitioner has met the burden of establishing a prima facie case in the first instance. Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012). As the Federal Circuit explained, "evidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made [under the Althen test] that the vaccine was a substantial factor in causing the injury in question." Id. (citing de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008); Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358-59 (Fed. Cir. 2006)).

In addition, the Federal Circuit has recognized that there may be situations in which the petitioner's injury is disputed, in which case the question of injury must be

[6] This determination is notably different from a medical diagnosis: "the function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury.'" Andreu, 569 F.3d at 1382 (quoting Knudsen, 35 F.3d at 549).

resolved before turning to the question of causation. Broekelschen, 618 F.3d at 1346. In these situations, the symptoms presented by the petitioner could be explained by multiple injuries, and the special master may be required to "first determine which injury [is] best supported by the evidence presented in the record before applying the Althen test." Id. The Federal Circuit has stated that "identifying the injury is a prerequisite to the [Althen] analysis" when "the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury [the petitioner] suffered." Id. Further, in the event that the special master determines that the petitioner cannot demonstrate that he or she actually suffers from the injury alleged, compensation may be denied without reaching an Althen analysis. Lombardi, 656 F.3d at 1353.

B. Petitioner's Objections to the Application of Broekelschen

Petitioner's motion for review is largely dedicated to challenging both the correctness of the Federal Circuit's Broekelschen decision and the chief special master's application of the test enumerated in that decision. Petitioner argues that Broekelschen was wrongly decided by the Federal Circuit and should not be followed. In addition, petitioner argues that the chief special master misapplied Broekelschen when she concluded that petitioner's injury for the purposes of the Vaccine Act was a bleeding cavernoma and not autoimmune transverse myelitis. Petitioner contends that all of the experts agreed that the injury at issue was the episode of transverse myelitis petitioner experienced in 2008 and thus the sole question before the court was whether the cause of that injury was the flu vaccine. More specifically, petitioner argues that the chief special master conflated the issues of "injury" and "causation," causing her to apply a

Broekelschen test when it was not required and heightening the burden on petitioner. According to petitioner, the question of alternate cause should have been considered during the respondent's portion of an Althen analysis instead.

With regard to petitioner's first contention, respondent argues that this court must follow Broekelschen regardless of whether it believes the decision to be correct and the court agrees. This court is bound by the precedent of the Federal Circuit and must follow it. Strickland v. United States, 423 F.3d 1335, 1338 & n. 3 (Fed. Cir. 2005); First Hartford Corp. Pension Plan & Trust v. United States, 194 F.3d 1279, 1290 n. 3 (Fed. Cir. 1999). As a result, this court cannot set aside the chief special master's decision simply because she relied on Broekelschen in making her decision.

With regard to petitioner's contention that the chief special master erred in her application of Broekelschen, respondent argues that the chief special master's decision to first determine whether petitioner's injury was a hemorrhage or bleed from a cavernoma rather than an autoimmune injury was proper under Broekelschen. Respondent argues that both the cavernoma and the autoimmune response could have been caused by the flu vaccine, making a determination of the actual injury that gave rise to the transverse myelitis necessary before moving to an Althen analysis. According to respondent, petitioner's transverse myelitis was a sequelae or secondary result of the injury, not the injury itself.

Whether Broekelschen applies where, as here, the questions of "cause" and injury" appear to be intertwined is greatly debated in petitioner and respondent's briefs. The court, however, finds that it is not necessary to resolve that question. Instead, because the

chief special master in this case also performed an Althen analysis as an alternative to her Broekelschen analysis, and the Althen analysis is fully dispositive of the issue, the court will turn to the parties' challenges to that analysis instead.[7] So long it was rational, based on the record as a whole, to find that petitioner had failed to demonstrate by a preponderance of the evidence that she sustained an autoimmune response to the 2008 flu vaccination and thus failed to demonstrate that there was a logical sequence of cause and effect, the chief special master's decision must be upheld.

C. Petitioner's Objections to the Application of Althen

Petitioner argues that the chief special master's Althen analysis must be overturned because (1) the record evidence established a logical sequence of cause and effect showing that petitioner had suffered an autoimmune response to her flu vaccination, causing inflammation in her spine that resulted in transverse myelitis, and (2) the chief special master impermissibly required petitioner to eliminate alternative causes rather than requiring respondent to prove them after shifting the burden. Petitioner argues that once she had established her prima facie case that the vaccine caused her injury, the burden should have shifted to respondent to prove that the cavernoma was the sole cause of petitioner's transverse myelitis.

Respondent argues that this court must uphold the chief special master's conclusion that "the record evidence strongly militates against a finding that Ms. Dillon

[7] At oral argument, in describing Broekelschen, respondent suggested that in this case it is possible to view the chief special master's Broekelschen analysis as a gloss on prong two of Althen rather than as a separate analysis altogether and thus it would not be necessary for the court to review the Broekelschen analysis if the Althen analysis were affirmed.

suffered from an autoimmune episode of transverse myelitis." Decision at 31. According to respondent, the resulting conclusion that petitioner failed to satisfy prong two of Althen and make a prima facie case is well supported by the record as a whole. In addition, respondent argues that the chief special master did not require petitioner to eliminate alternative causes; rather, respondent argues, the chief special master, consistent with Stone, properly considered the totality of the evidence. Relying on Stone, the respondent explained that the chief special master was allowed to consider evidence of other possible sources of injury in deciding "whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question" in addition to "the 'factors unrelated defense.'" Id. at 1379-80 (citing de Bazan, 539 F.3d at 1353; Pafford, 451 F.3d at 1358-59).

The court agrees with respondent that the chief special master's decision that petitioner did not suffer an autoimmune response to her flu vaccination and thus did not make out a prima facie case is supported by the record and therefore is not arbitrary or capricious. The court also agrees with respondent that the chief special master did not impermissibly shift the burden to petitioner to eliminate alternative causes and demonstrate that the cavernoma was not the cause of her transverse myelitis. Rather, the court agrees with respondent that the chief special master, consistent with Stone, properly considered all of the evidence, including the evidence purporting to demonstrate petitioner's lack of autoimmune response as well as the evidence regarding her cavernoma, in concluding that petitioner had failed to make a prima facie case.

In reaching this conclusion, the court is mindful that in an off-Table case such as this, the petitioner has the burden of satisfying all three prongs of the Althen test and that failure to meet any one of the three prongs is fatal to her claim. See, e.g., Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650 (2011) (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006)) ("A plaintiff must satisfy all three of Althen's prongs by preponderant evidence."). Second, the court is mindful of the very limited role it has in reviewing the chief special master's findings of fact. As the Federal Circuit has stated:

> The statute makes clear that, on review, the Court of Federal Claims is not to second guess the special masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366-67 (Fed. Cir. 2013) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)) (alteration in original). Thus, the court cannot "reweigh the evidence . . . [and must uphold the decision] if the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible." Id. at 1367 (quoting Lampe, 219 F.3d at 1363) (some alterations in original) (internal quotation marks omitted).

Here, based on the evidence presented to the chief special master with regard to the second prong of the Althen test, the court finds that the chief special master's decision must be affirmed. Specifically, under prong two of Althen, in order to establish a prima facie case the petitioner had the burden of establishing a logical sequence of cause and

effect between her receipt of the flu vaccination and an autoimmune response. Petitioner endeavored to prove that she had an autoimmune response to her vaccination by presenting evidence to show that she had an inflammatory reaction to the vaccine, which her experts explained proved an autoimmune response.

The respondent countered the petitioner's evidence with evidence to show that petitioner did not have an inflammatory reaction to the vaccine and thus did not suffer an autoimmune response to the flu vaccination in 2008. The testimony and exhibits presented by respondent in response to petitioner's theory included evidence that (1) symptoms that typically indicate an inflammatory reaction were lacking, including a lack of fever, a lack of significantly elevated white blood cell count, less diffuse sensory loss, lack of oligoclonal banding, and lack of protein in the cerebrospinal fluid; (2) petitioner did not have a significant response to her steroid treatment; (3) petitioner had received previous flu vaccines without incident; (4) her radiologic imaging was inconsistent with an inflammatory, demyelinating lesion because it did not diminish over time; (5) there was a cavernoma at the epicenter of the petitioner's MRI images at the time of her alleged autoimmune response; (6) there were hemosiderin deposits evident in petitioner's MRI images, which are indicators of past bleeding at the cavernoma site; and (7) autoimmune transverse myelitis does not cause hemosiderin deposits.

While the petitioner provided evidence to show that (1) the degree of transverse myelitis shown by petitioner's 2008 MRIs is too great to be explained by a spinal bleed; (2) there is no previously reported case of an adult experiencing swelling in six segments of the spine as a result of a bleed of the size of the small cavernoma at issue at the time of

the injury; (3) certain signatures in MRI images that would have indicated a spinal bleed are lacking; and (4) petitioner's treating physicians diagnosed her with an autoimmune response and opined that the petitioner's cavernoma was not associated with petitioner's transverse myelitis, the chief special master determined that this evidence was not sufficient to overcome respondent's evidence. The chief special master thus concluded that petitioner had failed to establish a logical sequence of cause and effect with regard to the vaccine.

Petitioner disagrees with the chief special master's conclusion based on the evidence presented. However, on review, this court cannot reweigh or reexamine the evidence presented to the chief special master. Deribeaux, 717 F.3d at 1366-67; see, e.g., Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1254 (Fed. Cir. 2011) ("This court does not reweigh the factual evidence or assess whether the special master correctly evaluated the evidence, nor does it examine the probative value of the evidence or the credibility of the witnesses."). Moreover, this court must affirm the chief special master if her decision is not "wholly implausible." Deribeaux, 717 F.3d at 1367. Here, in light of the evidence discussed above, the court finds that the chief special master's conclusion that petitioner did not have an autoimmune response to the flu vaccine and thus could not link the vaccine to her injury is not "wholly implausible." Accordingly, the court must affirm the chief special master's conclusion that petitioner failed to establish the logical sequence of cause and effect necessary to make a prima facie case under prong two of Althen.

Additionally, the court finds that petitioner's contention that the chief special master required petitioner to eliminate alternative causes and prove that her cavernoma was not the cause of her transverse myelitis is without merit. While the chief special master did use conclusory language with regard to her finding that the evidence indicated that petitioner had a bleeding cavernoma in her analysis of the second prong of Althen, that finding followed her first, and critical, finding that petitioner had failed to establish that she had an autoimmune response to her 2008 flu vaccination. Because the petitioner failed to establish a prima facie case that she had an autoimmune reaction to the 2008 flu vaccination, which was the basis for her claim, the issue of burden shifting did not arise. Petitioner's objections to the chief special master's Althen analysis on this ground also must be rejected.

IV. CONCLUSION

As the decision of the chief special master was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, petitioner's motion for review is **DENIED** and the chief special master's decision is **SUSTAINED**. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/Nancy B. Firestone
NANCY B. FIRESTONE
Judge